

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 12916-56	FOR FURTHER ACTION		see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.
International application No. PCT/CA 02/01772	International filing date (day/month/year) 22/11/2002	(Earliest) Priority Date (day/month/year) 23/11/2001	
Applicant DUOJECT MEDICAL SYSTEMS INC			

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 7 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

- a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).
- b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing :
- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. ☒ **Certain claims were found unsearchable** (See Box I).

3. ☐ **Unity of invention is lacking** (see Box II).

4. With regard to the **title**,

- ☒ the text is approved as submitted by the applicant.
- ☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

- ☒ the text is approved as submitted by the applicant.
- ☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No.

- ☒ as suggested by the applicant.
- ☐ because the applicant failed to suggest a figure.
- ☐ because this figure better characterizes the invention.

1
☐ None of the figures.

INTERNATIONAL SEARCH REPORT

International Application No

PCT/CA 02/01772

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M5/24 B65B3/00 A61L2/20

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61M B65B A61L

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2 860 635 A (WILBURN EDGAR H) 18 November 1958 (1958-11-18)	1,5-7
Y	column 7, line 1 -column 8, line 47; figure 1	11-14, 17,22,23 18,29
A	---	
Y	GB 2 249 727 A (DUOJECT INC) 20 May 1992 (1992-05-20)	11,12, 17,18, 22-29
A	page 3, line 23 -page 5, line 17; figures 2,3	1,5-10, 13,14, 19-21, 30-32

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☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents:

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- * & * document member of the same patent family

Date of the actual completion of the international search

14 March 2003

Date of mailing of the international search report

28/03/2003

Name and mailing address of the ISA

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Riörklund A

INTERNATIONAL SEARCH REPORT

International Application No

PCT/CA 02/01772

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 95 17915 A (EISAI CO LTD ;WATANABE SUMIO (JP); IKEUCHI TAKAYUKI (JP); WATANABE) 6 July 1995 (1995-07-06) page 11, paragraph 5 -page 12, paragraph 4; figures 20-23 ---	13,14
Y	EP 0 298 585 A (DUOJECT INC) 11 January 1989 (1989-01-11) cited in the application	18,29
A	column 2, line 15 -column 3, line 31; figures 1-12 column 5, line 25 - line 46 column 7, line 51 -column 8, line 21 ---	1,5-14, 17, 19-28, 30-32
Y	WO 99 45984 A (CARRE PATRICK ;CAMPOS JORGE (MX); AGUERO SERVIN MARIO DE (MX); BEC) 16 September 1999 (1999-09-16) page 30, line 13 -page 31, line 5; figures 1-11 page 16, line 2 -page 17, line 9 -----	24-28

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1, 5-14

Claims 1, 5-14 define an assembly for forming a barrel of a prefilled syringe wherein a piston support means supports the piston such that a gap exists between the upper surface of the piston and the body of the syringe barrel, thereby permitting sterilization of the syringe body and the piston by a sterilizing gas.

2. Claims: 17-21

Claims 17-21 define a method for producing a syringe barrel for a pre-filled syringe wherein the barrel is filled and capped using equipment for filling and capping pharmaceutical barrels.

3. Claims: 22-32

Claims 22-32 define a method for producing a barrel for use in a pre-filled syringe wherein an assembled barrel is maintained in a sterile environment until it is ready to be filled

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.2

Claims Nos.: 2-4, 15-16

Present claims 2-4, 15-16 relate to a product defined by reference to a desirable characteristic or property, namely

That, the sleeve permits the assembly for forming a barrel of a pre-filled syringe to be conveyed upright without tipping.

1.1 Claim 2 only states a wished result to be achieved and contains no technical features contrary to Rule 6.3(a) PCT.

1.2. Claim 3 only states that a certain diameter and height of the sleeve prevents tipping of the assembly when conveyed through an apparatus for filling and capping vials. The person skilled in the art has no possibility to decide what the height and diameter of the sleeve are as they depend on a multitude of parameters (e.g. speed of conveying, acceleration of the assembly, friction between assembly and conveyor belt, centre of gravity of the assembly which in turn depends on the materials chosen for the syringe body, piston, sleeve) and changes between different filling and capping machines, and also on the different drugs filled (liquid, powder). Claims 4, 15-16 defines further embodiments dependent on claim 3.

Therefore, the claims lack clarity (Article 6 PCT). An attempt is made to define the product by reference to a result to be achieved. This lack of clarity in the present case is such as to render a meaningful search over the whole of the claimed scope impossible. Consequently, the search has been carried out for those parts of the claims which appear to be clear, supported and disclosed, namely those parts relating to the products claimed in claims 1, 5-14 and methods in claims 17-32

The applicant's attention is drawn to the fact that claims, or parts of claims, relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/CA 02/01772

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☒ Claims Nos.: 2-4, 15-16
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
see FURTHER INFORMATION sheet PCT/ISA/210
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☒ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/CA 02/01772

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 2860635	A	18-11-1958	DE 1082705 B	02-06-1960
			FR 1203606 A	20-01-1960
			GB 847914 A	14-09-1960
GB 2249727	A	20-05-1992	US 5137511 A	11-08-1992
			AU 661282 B2	20-07-1995
			AU 8923491 A	11-06-1992
			CA 2096662 A1	15-05-1992
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			FI 932219 A	14-05-1993
			JP 3313706 B2	12-08-2002
			JP 6504452 T	26-05-1994
			NO 931611 A	14-05-1993
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			WO 9517915 A2	06-07-1995
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			AT 96042 T	15-11-1993
			AU 623594 B2	21-05-1992
			AU 1757988 A	12-01-1989
			CA 1295525 A1	11-02-1992
			CA 1334070 A1	24-01-1995
			DE 3885018 D1	25-11-1993
			DE 3885018 T2	24-03-1994
			EP 0298585 A1	11-01-1989
			ES 2047546 T3	01-03-1994
			GB 2210268 A	07-06-1989
			IE 63513 B1	03-05-1995
			JP 1131671 A	24-05-1989
			JP 2801207 B2	21-09-1998
			US 5554125 A	10-09-1996
			US 5137511 A	11-08-1992
			US 5364369 A	15-11-1994
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			AU 3001399 A	27-09-1999
			EP 1061974 A1	27-12-2000
			EP 1061975 A1	27-12-2000
			JP 2002505980 T	26-02-2002
			JP 2002505921 T	26-02-2002
			WO 9945984 A1	16-09-1999
			WO 9945985 A1	16-09-1999
			US 6189292 B1	20-02-2001
			US 6164044 A	26-12-2000
			US 6263641 B1	24-07-2001
			US 6250052 B1	26-06-2001
			US 2002069616 A1	13-06-2002